



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,091	12/04/2001	Jeong Gun Lee	041501-5485	8023

9629 7590 04/15/2003

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 04/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/000,091

Applicant(s)

LEE ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 10-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-9 in papers filed 5 March 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-9 are indefinite in Claim 1, step (b) for the recitation "placing a target.....for hybridization of the probe DNA" because it is unclear whether the recitation is a method step of hybridization or whether the recitation is merely a step of placing the target on the chip such that hybridization could occur at some future time. It is suggested that Claim 1 be amended to clarify e.g. replace "for hybridization of" with "to thereby hybridize".

b. Claims 1-9 are indefinite in Claim 1, step (c) for the recitation "the hybridized DNA" because the recitation lacks proper antecedent basis in step (b). It is suggested that Claim 1 be amended to provide proper antecedent basis e.g. at the end of step (b) insert, "to provide hybridized DNA".

Art Unit: 1634

c. Claims 1-9 are indefinite in Claim 1, step (d) for the recitation "the DNA" because the recitation lacks proper antecedent basis in the claim. Therefore, it is unclear whether the recitation refers to the "target DNA" or "probe DNA" of step (b) or the "hybridized DNA" of step (c). It is suggested that Claim 1 be amended to provide proper antecedent basis.

d. Claims 1-9 are indefinite in Claim 1, step (e) for the recitation "for causing reaction between the intercalator and the electrochemical reaction fluid" because it is unclear whether the reaction occurs or whether the recitation merely defines the applied voltage as being preset. It is suggested that Claim 1 be amended to clarify e.g. replace "for" with "thereby".

e. Claims 2-4 are indefinite in Claim 2 for the recitation "wherein step (a) includes the steps of;...." because it is unclear whether step (a) further includes the steps recited in Claim 2 or whether the recited steps replace step (a) of Claim 1. It is suggested that Claim 2 be amended to clarify.

f. Claims 2-4 are indefinite in Claim 2 for the recitations "the first time" and "the second time" because the recitations lack proper antecedent basis in Claim 1. It is suggested that Claim 2 be amended to provide proper antecedent basis e.g. replace "the" with "a".

g. Claim 4 is indefinite for the recitation "PCB" because the recitation is an abbreviation the meaning of which may change over time. It is suggested that Claim 4 be amended to recite the complete term.

h. Claim 7 is indefinite for the recitation "wherein step (b) includes the steps of;...." because it is unclear whether step (b) further includes the steps recited in Claim 7 or whether the recited steps replace step (b) of Claim 1. It is suggested that Claim 7 be amended to clarify.

i. Claim 7 is further indefinite for the recitations "applying a first voltage to the chip for hybridizing" and "applying a second voltage to the chip for removing" because it is unclear whether the recitations are method steps of hybridization and removing in which hybridization and removing occurs. It is suggested that Claim 7 be amended to clarify e.g. replace "for hybridizing" with "to thereby hybridize" and replace "for removing" with "to thereby remove".

Art Unit: 1634

j. Claim 7 is also indefinite for the recitation "removing not hybridized remained DNAs" because the syntax is confusing. It is suggested that Claim 7 be amended to clarify e.g. delete "remained".

k. Claim 8 is indefinite for the recitation "the intercalators not fixed to the hybridized DNA" because "not fixed" lacks proper antecedent basis in the "intercalating" of Claim 1. It is suggested that Claim 8 be amended to provide proper antecedent basis e.g. replace "fixed" with "intercalated".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-2 and 5-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Hashimoto et al (U.S. Patent No. 5,776,672, issued 7 July 1998).

Regarding Claim 1, Hashimoto et al disclose a method for detecting DNA comprising: immobilizing a probe DNA on a chip, placing a target DNA on the chip to hybridize the target and probe DNA, intercalating an intercalator to the hybridized DNA, introducing an electrochemiluminescent reaction fluid into the chip, applying a preset voltage to cause a reaction between the intercalator and reaction fluid, and detecting and analyzing light from the reaction (Abstract; Column 4, lines 5-54; Examples 7-11, Columns 17-20; and Claims 1-9).

Regarding Claim 2, Hashimoto et al disclose the method wherein immobilizing the probe DNA includes the steps of washing an electrode, dipping the electrode in a mixed solution containing the probe DNA and washing a second time to immobilize the DNA (Column 8, line 36-Column 10, line 15 and Example 24, Column 39, lines 5-30).

Regarding Claim 5, Hashimoto et al disclose the method wherein the intercalator is selected from daunorubicin, nogalamycin, doxorubicin, and DAPI(4',6-diamidino-2-phenylindole), or, one selected from a material obtained by bonding proline, oxalic acid, or TPA (tripropylamine) with Hoechst 33258, quinacrine, or acridity orange(Column 4, lines 5-54).

Regarding Claim 6, Hashimoto et al disclose the method wherein the electrochemiluculent reaction fluid is one selected from Tris(2,2'-bipyridyl)ruthenium(II)(Ru(bpy)₃²⁺), Tris(2,2'-bipyridyl)osmium(II)(Os(bpy)₃²⁺), and Tris (1,10-phenanthroline ruthenium (II) Ru(phen)₃²⁺ (Column 4, lines 5-54).

Regarding Claim 7, Hashimoto et al disclose the method wherein step (b) includes placing the target DNA on the chip, applying a first voltage to hybridize the probe and target, and applying a second charge for removing not hybridized DNA (Column 13, lines 21-30).

Regarding Claim 8, Hashimoto et al disclose the method wherein step (c) further includes washing the intercalators not intercalated to the hybridized DNA with a buffer solution (Column 12, lines 37-42).

Regarding Claim 9, Hashimoto et al disclose the method wherein the preset voltage in step (e) is 0.5-1.20 V (Column 13, lines 13-20).

6. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (U.S. Patent No. 6,342,359, filed 29 September 2000).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 1, Lee et al disclose a method for detecting DNA comprising: immobilizing a probe DNA on a chip, placing a target DNA on the chip to hybridize the target and probe DNA, intercalating an intercalator to the hybridized DNA, introducing an electrochemiluminescent reaction fluid into the chip, applying a preset voltage to cause a reaction between the intercalator and reaction fluid, and detecting and analyzing light from the reaction (Column 6, line 30-Column 8, line 67).

Regarding Claim 2, Lee et al disclose the method wherein immobilizing the probe DNA includes the steps of washing an electrode, dipping the electrode in a mixed solution containing the probe DNA and washing a second time to immobilize the DNA (Column 6, line 30-Column 7, line35).

Regarding Claim 3, Lee et al disclose the method wherein step (a) includes washing an electrode the first time, dipping the electrode in a mixed solution containing the probe DNA and washing the electrode the second time thereby immobilizing the DNA (Column 6, line 30-Column 7, line35).

Regarding Claim 4, Lee et al disclose the method wherein the first washing includes the steps of dipping the electrode in piranha solution and water, the mixed solution containing probe DNA and w-hydroxy-undecanethaiol 3 or 3-mercaptopropionic acid dissolved in ethanol/octane and the second washing includes washing in ethanol and water 6, line 30-Column 7, line35).

Regarding Claim 5, Lee et al disclose the method wherein the intercalator is selected from daunorubicin, nogalamycin, doxorubicin, and DAPI(4',6-diamidino-2-phenylindole), or, one selected from a material obtained by bonding proline, oxalic acid, or TPA (tripropylamine) with Hoechst 33258, quinacrine, or acridity orange (Column 4, lines 45-67).

Regarding Claim 6, Lee et al disclose the method wherein the electrochemiluculent reaction fluid is one selected from Tris(2,2'-bipyridyl)ruthenium(II)(Ru(bpy)₃²⁺), Tris(2,2'-bipyridyl)osmium(II)(Os(bpy)₃²⁺), and Tris (1,10-phenanthroline ruthenium (II) Ru(phen)₃²⁺ (Column 4, lines 45-67).

Regarding Claim 7, Lee et al disclose the method wherein step (b) includes placing the target DNA on the chip, applying a first voltage to hybridize the probe and target, and applying a second charge for removing not hybridized DNA (Column 8, line 62-Column 9, line 15).

Regarding Claim 8, Lee et al disclose the method wherein step (c) further includes washing the intercalators not intercalated to the hybridized DNA with a buffer solution (Column 8, lines 54-61).

Regarding Claim 9, Lee et al disclose the method wherein the preset voltage in step (e) is 0.5-1.20 V (Column 8, lines 62-67).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al (U.S. Patent No. 5,776,672, issued 7 July 1998) in view of Blackburn et al (U.S. Patent No. 6,264,825, filed 23 June 1999).

Regarding Claim 4, Hashimoto et al disclose a method for detecting DNA comprising: immobilizing a probe DNA on a chip, placing a target DNA on the chip to hybridize the target and probe DNA, intercalating an intercalator to the hybridized DNA, introducing an electrochemiluminescent reaction fluid into the chip, applying a preset voltage to cause a reaction between the intercalator and reaction fluid, and detecting and analyzing light from the reaction (Abstract; Column 4, lines 5-54; Examples 7-11, Columns 17-20; and Claims 1-9) wherein the electrode is formed of gold (Column 8, lines 44-54) and the probe DNA has a thiol (i.e. mercapto) functional group at a 5' phosphate position (Column 8, line 60-Column 9, line 32) but they are silent regarding the composition of the chip. However, methods for detecting DNA utilizing silicon chips comprising gold electrodes were well known in the art at the time the claimed invention was made as taught by Blackburn et al (Example 1-2: Column 89, line 5-Column 90) wherein the application of gold electrodes onto the chip provides a pattern of electrodes for conducting multiple detection assays simultaneously (Column 2, line 60-Column 3, line 15). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known silicon chip substrate of Blackburn et al

Art Unit: 1634

to the substrate of Hashimoto et al and to apply the gold electrodes of Hashimoto onto the silicon chip to thereby provide a pattern on electrodes on the chip for the obvious benefits of conducting multiple detection assays simultaneously as taught by Blackburn et al (Column 2, line 60-Column 3, line 15 and Examples 1-2).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13 and 15 of U.S. Patent No. 6,342,359. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to similar methods for detecting DNA and differ only in the arrangement of limitations within the claim sets. For example, Claim 13 of '359 is drawn to a method utilizing their device as claimed in Claim 1 which comprises probe DNA immobilized on a chip and the method recites the steps of oxidizing bipyridyl complexes or derivative thereof. Similarly, instant Claim 1 is drawn to a method which recites the method

Art Unit: 1634

step of immobilizing probe DNA on a chip and recites the method step of introducing an electrochemicaluminescent reaction fluid which depend claim 6 defines as bipyridyl complexes and derivatives. As such, the '359 claims and instant claims are drawn to very similar methods encompassing the same limitations and therefore the claim sets are not patentably distinct.


Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
April 9, 2003